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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/247,219 02/10/99 TOMASULA

P 862.004US1

IM52/0622

EXAMINER

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ART UNIT

PAPER NUMBER

1761

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/247,219	Applicant(s) TOMASULA, PEGGY M.	
	Examiner DuBois	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-6,9,11-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-6,9,11-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 4-6, 8-9, 11-13 and 15-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlstrom (U.S. Patent 5,006,349) in view of Tomasula (U.S. Patent 5,006,349).

Response to Arguments

Applicant's arguments filed on May 21, 2001 have been fully considered but they are not persuasive.

The applicant argues that Dahlstrom does not teach the following: 1) carbon dioxide; 2) a holding step; 3) gradual depressurization; 4) further separation of the protein and 5) the final concentration of the product. However, the applicant neglects the teaching of Tomasula. The rejection is based on Dahlstrom in view of Tomasula. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Art Unit: 1761

Dahlstrom teaches a protein product and a process for continuously reacting protein solution by direct acidification to produce food products (U.S. Patent 5,006,349, col. 2, lines 30-35). The protein stream may be derived from a number of products including soy milk and cereal protein slurries (col. 3, lines 30-35). In example 11, Dahlstrom teaches a milk-soy protein cheese product. Dahlstrom teaches that a coagulum of the protein stream and other ingredients can be made. It would be expected by one of ordinary skill in the art that the protein source would have a protein concentration of less than 80% by total weight of the product. Furthermore, it is noted that the claim uses "comprising" as the transitional phrase. The claim does not exclude other sources of protein. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

After the mixture is prepared, a sonolator is used at 800 psi. As the process continues, the pressure is reduced to 400 psi (col. 8, lines 40-60). The pH of the mixture was 5.2. However, Dahlstrom teaches that the pH can be optimized to vary the consistency of the product.

As noted before in previous Office Actions, Dahlstrom is silent as to the use of a carbon dioxide to precipitate protein. However, Dahlstrom teaches that carbonic acid

Art Unit: 1761

can be added into a process for producing protein products. Tomasula teaches a process for the continuous production and removal of products from a high-pressure system. In the process, Tomasula broadly teaches that carbon dioxide under pressure can precipitate proteins (U.S. Patent 5,432,265, col. 1, lines 53-57). Furthermore, Tomasula teaches that by injecting carbon dioxide and increasing the pressure, carbonic acid is formed which lowers the pH. Tomasula teaches that this is desirable as the lower pH precipitates the protein. As Tomasula teaches that carbon dioxide can easily be converted into carbonic acid, it would have been obvious to one of ordinary skill in the art to incorporate carbon dioxide or carbonic acid into the process.

Tomasula further teaches that in order to allow the solid products to exit the system while at the same time maintaining high pressure in the reactor, a high-pressure pump is operated in reverse to gradually reduce the pressure at the exit line to atmospheric pressure (col. 3, lines 10-15).

Tomasula teaches that the section of the extruder can also include an optional holding tube to increase residence time (col. 3, lines 60-65).

The applicant further argues that the carbon dioxide provides the important function of actually maintaining the desired pressure in the instant invention. However, the actual source of the pressure is not disclosed in the claimed invention. The claimed invention only recites that the carbon dioxide is administered in to the system under pressure. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., maintaining the pressure of the system) are not recited in the rejected claim(s).

Art Unit: 1761

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The applicant further argues that Dahlstrom fails to teach a holding step and the gradual depressurization of the product stream. However, as noted above, Tomasula teaches these limitations. Furthermore, one of ordinary skill in the art would be motivated to combine Tomasula and Dahlstrom. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Tomasula and Dahlstrom are both concerned with obtaining protein concentrates.

The applicant further argues that the instant invention is further distinguished from the prior art because the claimed invention recites a separation step. However, Tomasula teaches that following removal from the system, the solid products may be further separated as necessary by conventional means such as settling, centrifugation and other methods. It would be obvious that the final concentration of the product would be affected by the further separation means. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the

Art Unit: 1761

prior art unless there is evidence indicating such concentration or temperature is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40C and 80C and an acid concentration between 25 and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100C and an acid concentration of 10%). See also *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

The applicant further argues that the injection of carbon dioxide would be impossible with the use of a sonolator as used in the examples of Dahlstrom. However, the record does not support this argument. Furthermore, Dahlstrom does not strictly limit the invention to just a sonolator (col. 3, lines 10-20).

As the rejection of Dahlstrom in view Tomasula teach each process step, the rejection of claims 2, 4-6, 8-9, 11-13, 15-16. See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975,

Art Unit: 1761

5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious).

Finally, Applicants' attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in the fact situation of the instant case, and wherein the Court stated on page 234 as follows:

This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coercion or cooperative relationship between the selected ingredients which produces a new, unexpected, and useful function. *In re Benjamin D. White*, 17 C.C.P.A (Patents) 956, 39 F.2d 974, 5 USPQ 267; *In re Mason et al.*, 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

Conclusion

1. No claim is allowed.
2. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1761

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiring concerning this communication or earlier communications from the examiner should be directed to Philip DuBois whose telephone number is (703) 305-0508. The examiner can normally be reached on Monday through Friday from 8:00 to 5:30. The examiner is not in the office the second and fourth Fridays of each month.

4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703)-308-0756. The fax number for the group is (703)-308-3959.

5. Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0661.

Philip DuBois

11/19/00

A handwritten signature in black ink, appearing to read 'C. Sherrer', with a long horizontal line extending to the right.

**CURTIS SHERRER
PATENT EXAMINER**